IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

E.G., a minor, by CHRISTINA RAQUEL, individually and as parent and next friend of E.G.,	)	Case No. 15-cv-702-NJR-SCW
Plaintiffs,	)	TRIAL DEMANDED ON ALL COUNTS
v.	)	
ABBOTT LABORATORIES INC.,	)	
Defendant.	)	

DEFENDANT'S RULE 50(a) MOTION FOR JUDGMENT AS A MATTER OF LAW WITH SUPPORTING BRIEF

As permitted by the Court, Abbott respectfully submits this written Rule 50(a) Motion for Judgment as a Matter of Law in addition to the oral motion counsel presented yesterday. Based on the evidence proffered in Plaintiffs' case-in-chief, "a reasonable jury would not have a legally sufficient evidentiary basis" to find for them under Fed. R. Civ. P. 50(a):

- Abbott's warnings to Ms. Raquel's prescribing physicians about the risk of spina bifida were adequate as a matter of law.
- Abbott did not negligently fail to warn about birth defects other than spina bifida, but in any case, any inadequacy in those warnings is irrelevant to Plaintiffs' claim based on spina bifida.
- Plaintiffs failed to proffer legally sufficient evidence that any alleged inadequacy in the warnings was a substantial factor in causing E.G.'s injuries. No reasonable jury could find that if Abbott had provided different warnings to Ms. Raquel's prescribing physicians, she would not have been prescribed and taking Depakote when E.G. was conceived in May 2006. Dr. Han's testimony does not provide legally sufficient evidence to the contrary.
- No reasonable jury could find that Plaintiffs have shown by clear and convincing evidence that Abbott's conduct amounted to malice, oppression, or fraud, or that any conduct they claim is blameworthy caused E.G.'s injuries. An award of punitive damages on these facts would violate California substantive law and federal due process.

Plaintiffs' have failed to submit legally sufficient evidence that (1) Abbott knew or reasonably should have known that Depakote was dangerous or unreasonably dangerous when prescribed by physicians in a reasonable foreseeable manner, (2) Abbott knew or reasonably should have known of the danger, (3) Abbott failed to adequately warn Ms. Raquel's prescribing physicians of the danger or instruct on the safe use of Depakote[1]; (4) a reasonably prudent manufacturer under the same or similar circumstances would have warned of the danger or instructed on the safe use of Depakote, [2] or (5) Abbott's alleged failure to warn was a substantial factor in causing E.G.'s injuries. Plaintiffs' proof is also legally insufficient to prove that one or more officers, directors, or managing agents of Abbott committed, authorized, or knew of and adopted and approved conduct constituting "malice," "fraud," or "oppression," as defined by California law, or that any such conduct or action was a substantial factor in causing E.G.'s injuries.

ARGUMENT

I. No reasonable jury could find that Abbott failed to act in a reasonably prudent manner in providing warnings to Ms. Raquel's prescribing physicians.

A. The injury at issue is spina bifida. Abbott provided warnings about the risk of spina bifida were clear, direct and accurate, and adequate.

Abbott and Plaintiffs' regulatory expert Dr. David Kessler agree on one point: "*Spina bifida risk is in the label*." (Ex. A, 5/25/17 Trial Tr. at 502:11-12 (emphasis added).) It is undisputed that the 2006 Depakote label contained a Black Box warning about the risk of neural

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[1] California applies the learned intermediary doctrine, meaning the drug company must warn the doctor, not the patient. *Carlin v. The Superior Court of Sutter County*, 13 Cal. App. 4th 1104, 1112-13 (1996).

[2] Because they have elected to proceed on a negligence theory, Plaintiffs must prove not only that Abbott failed to warning of a known or reasonably knowable risk, but that it did not act as a reasonably prudent manufacturer in providing warnings to physicians. *Carlin*, 13 Cal. App. 4th at 1112-13. No reasonable jury could find they have established either prong.

tube defects, including spina bifida, the injury for which Plaintiffs seek damages in this case. Ex. B, Trial Ex. Px1871-0024.) The Warnings section of the label further states that the estimated risk of neural tube defects is 1-2%—an estimate that Plaintiffs' experts do not dispute. The Black Box Warning also refers physicians to the Patient Information Leaflet at the end of the label, which describes the background rate of spina bifida in the United States as 0.1-0.2% and thus informs doctors that the medication increases the risk of spina bifida by 10 to 20 times over the background rate. Depakote was in 2006 a Category D drug, meaning that there was positive evidence of human fetal risk associated with its use. No other competitive medication had a Black Box Warning about birth defects, or provided as much information about birth defects as the 2006 Depakote label—as Dr. Heimburger testified without contradiction. (Ex. C, 5/30/17 Trial Tr. 849:19-25.)

"A written warning is adequate if it directly warns in plain and explicit terms *of the specific risk that has caused injury to the plaintiff*."[3] Courts applying California law have not hesitated to rule that warnings are adequate as a matter of law when those warnings describe the very injury complained of in plain and explicit terms.[4] Abbott's spina bifida warnings did just

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[3] *Utts v. Bristol-Myers Squibb Co.*, -- F. Supp. 3d --, 2017 WL 1906875, at *20 (S.D.N.Y. May 8, 2017) (applying California law) (emphasis added) (citing *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 467 (Cal. Ct. App. 1985), *disapproved on other grounds by Brown v. Superior Court*, 44 Cal.3d 1049, 1069–70 (Cal. 1988)); *see also Anderson*, 810 P.2d at 558 (negligent failure-to-warn claims requires a plaintiff to "prove that a manufacturer or distributor did not warn *of a particular risk* for reasons which fell below the acceptable standard of care." (emphasis added).

[4] *See, e.g.*, *In re Accutane Prods. Liab.*, Nos. 8:04–MD–2523–T–30TBM, 8:14–CV–157–T–30TBM, 2014 WL 7896548, at *4 (M.D. Fla. Sept. 23, 2014) (applying California law) (granting summary judgment where drug label "plainly and prominently identified inflammatory bowel disease by name" as a possible risk); *In re Baycol Prods. Litig.*, No. 02-3904 (MJD/SRN), 2008 WL 6155700, at *7–10 (D. Minn. Sept. 22, 2008) (applying California law) (granting summary judgment drug warnings were "clear, direct, and approved by the FDA" and disclosed the "precise risk encountered by the plaintiff"); *Dash v. Roche Labs.*, 74 F.3d 1245 (9th Cir. 1996) (unpublished) (applying California law) 245

that. Because no reasonable jury could find that Abbott negligently failed to warn about the risk of spina bifida, the Court should grant Abbott judgment as a matter of law.

B. No reasonable jury could find that Abbott negligently failed to warn about other birth defects, but regardless, Abbott is entitled to judgment as a matter of law as to Plaintiffs' spina bifida claim.

Spina bifida is the only injury for which Plaintiffs seek relief in this case. But Abbott adequately warned about the risk of spina bifida. In an effort to sidestep those plainly adequate warnings, Plaintiffs' experts largely focused their criticism on the fact that the 2006 Depakote did not include an overall incidence rate for all birth defects, including ones not at issue in this case. This effort is unavailing, and does not defeat judgment as a matter of law. First, Abbott's warnings, including specific reference to other congenital defects, the Black Box Warning referencing Depakote's "TERATOGENIC POTENTIAL," and its Category D status, establish that Abbott acted reasonably in providing Ms. Raquel's prescribing physicians with information about birth defects other than spina bifida.

Second, any alleged inadequacy of warnings about other birth defects is irrelevant. The only injury for which Plaintiffs' seek recovery is spina bifida—a risk Abbott adequately warned about. While E.G. was born with thumb polydactyly in addition to spina bifida, this condition was successfully surgically corrected and Plaintiffs apparently seek no damages for it. [5] And

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(affirming summary judgment for defendants after finding that defendants' warning accompanying Accutane was adequate as a matter of law because the "package insert and brochure clearly and explicitly warned . . . of the risk that the use of Accutane might result in a persistent or permanent dry eye condition"); *cf. In re Related Asbestos Cases*, 543 F. Supp. 1152, 1160 (N.D. Cal. 1982) (barring plaintiffs from referring to the risk of cancer from asbestos exposure when the plaintiff did not have cancer).

[5] E.G. also was born with patent foramen ovale, which can cause a heart murmur. But according to Dr. Curry, this condition is "innocent" and "kind of normal", has not impacted E.G.'s cardiac function and structure, and is not an in at issue in the case. (Ex. D, 5/31/17 Trial Tr. 1022:23-1025:10.)

thumb polydactyly and spina bifida are "completely separate birth defects" according to their expert Dr. Curry. (Ex. D, 5/31/17 Trial Tr. 979:6-7.) An adequate warning about one injury is not rendered inadequate because the product maker failed to warn about a "completely separate" injury. Rather, adequacy under California law is judged in terms of the specific risk that a product has allegedly caused to the plaintiff.[6] Even if California law were unclear, this Court should decline Plaintiffs' invitation to expand it in the novel and illogical manner Plaintiffs suggest.[7]

Because Abbott adequately warned about the very condition at issue, the Court should grant Abbott judgment as a matter of law on Plaintiffs' negligent failure to warn claim. In the alternative (and if the Court does not grant judgment for lack of causation), Abbott respectfully asks the Court to grant partial judgment as to Plaintiffs' claims and damages based on E.G.'s spina bifida, leaving only his thumb injury for the jury's consideration, and to instruct the jury accordingly. Neither California law nor common sense permit Plaintiffs to use E.G.'s thumb injury as the pretext to recover millions of dollars for his spina bifida when Abbott unquestionably provided an adequate warning about spina bifida.

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[6] This legal principle is consistent with the holdings of courts across the country. *See, e.g., Mills v. United States*, 764 F.2d 373, 379 (5th Cir. 1985) (applying Louisiana law) ("The question of the adequacy of the warnings must be confined to consideration of whether the warnings were sufficient to inform the plaintiff of the risk of the particular condition or disease which allegedly caused his in or death."); *In re Rezulin Prods. Liab. Litig.*, 2004 WL 1802960 (S.D.N.Y. Aug. 13, 2004), *vacated on other grounds*, 2004 WL 2009445 (S.D.N.Y. Sept. 8, 2004) (applying Texas law) (allegations about risks of injuries that plaintiffs did not experience was "beside the point" and irrelevant) *Peterson v. Parke Davis & Co.*, 705 P.2d 1001, 1004 (Colo. Ct. App. 1985) ("[T]he request for an instruction that Parke Davis had a duty to warn of all known dangers was properly denied. In a failure to warn case, the plaintiff has the burden of proving that the manufacturer gave inadequate warning of the danger which caused the in.").

[7] *See Gust K. Newberg Const. Co. v. E.H. Crump & Co.*, 818 F.2d 1363 (7th Cir. 1987) (federal court sitting in diversity is ill-suited to expand state law).

C. Plaintiffs' other failure-to-warn arguments are legally untenable, unsupported by legally sufficient evidence, and/or irrelevant.

Plaintiffs' other criticisms of the 2006 Depakote warnings and Abbott's conduct do not defeat Abbott's motion. A clear and accurate warning to physicians about the precise risk at issue is not rendered inadequate because it does not include comparative risk information about other drugs, or express incidence rates in a particular way (*e.g.* odds ratio versus absolute risk), or instruct physicians to use the drug as a "last resort." There is no independent "duty to test" under California law,[8] prospective studies to look for teratogenic potential would be unethical, and no reasonable jury find that any earlier study or testing would have generated data relevant to this case anyway.

II. Plaintiffs failed to proffer legally sufficient evidence that any different warning proposed by them would have prevented E.G.s prenatal exposure to Depakote.

California law is clear that "inadequacy of the warning and causation are separate elements of Plaintiffs' affirmative burden."[9] Even if Abbott's warnings had been inadequate, Plaintiffs still had to prove the inadequacy caused E.G.'s injuries."[10] Here, that means Plaintiffs had to provide legally sufficient evidence that Ms. Raquel would not have been prescribed and

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8 *See Phillippi v. Stryker Corp.*, 2010 WL 2650596, at *2 (E.D. Cal. July 1, 2010) (where warnings are adequate, "the manufacturer's alleged failure to test [the] product cannot, by itself, either cause in or be a source of liability of the manufacturer. Imposing liability for breach of a purported 'independent duty to conduct long-term testing' would be beyond the pale of any known California tort doctrine, because, inter alia, the causal link between Plaintiff's known harm, and the unknown outcome of the hypothetical testing is entirely speculative.")

9 *Tucker v. Wright Med. Tech., Inc.*, 2013 WL 1149717, at *16 (N.D. Cal., Mar. 19, 2013) (emphasis in original); *see also Thomas v. Abbott Labs.*, 2014 WL 4197494, at *5 (C.D. Cal., July 29, 2014) (plaintiff must establish the "separate elements" of inadequacy and causation)).

10 *Stanley v. Novartis Pharm. Corp.*, 11 F. Supp. 3d 987, 1002-03 (C.D. Cal. 2014), quoting *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990-991 (C.D. Cal. 2001).

taking Depakote at the time of E.G.'s conception in May 2006 if Abbott had provided different warnings.[11] They did not meet this burden.

A. No reasonable jury could find that Ms. Raquel would not have been prescribed and taking Depakote at the time of E.G.'s conception if Abbott had provided different warnings.

Of the three prescribers whose testimony the jury heard in Plaintiffs' case (Drs. Franklin and Giese via deposition and Dr. Han live at trial) all three were aware of the teratogenic effects of Depakote when they prescribed it to Ms. Raquel. (Ex. E, 12/3/15 Deposition of Dr. Arthur Giese, played on 5/31/17 ("Giese Dep.") at 76:14-774, 77:9-12, 12/22/15; Ex. F, Deposition of Robert Franklin played on 5/26/17 ("Franklin Dep.") at 25:18-26:6, 27:16-23; Ex. G, 6/5/07 Trial Tr. at 1154:12-16.) The failure to warn of a risk already known is not actionable.[12]

Plaintiffs also failed to proffer legally sufficient evidence that different warnings more likely than not would have prevented E.G.'s prenatal exposure to Depakote.

Dr. Franklin. It is undisputed that Dr. Franklin first prescribed Depakote for Ms. Raquel. Dr. Franklin did not testify he would not have prescribed Depakote for Ms. Raquel had he been given different Plaintiffs' proposed warnings by Abbott, including the 10% overall risk Plaintiffs rely on. Plaintiffs could have asked him whether that made a difference at his deposition, or called him live at trial to ask that question. They did not, and this failure precludes them from demonstrating Dr. Franklin would not have prescribed Depakote to Ms. Raquel. [13]

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[11] *See Motus*, 196 F. Supp. 2d at 995 (granting summary judgment where plaintiff produced no evidence that physician who prescribed Zoloft six days before the decedent's suicide would have acted differently if provided an "adequate" warning).

[12] *Rosburg v. Minn. Mining & Mfg. Co.*, 181 Cal. App. 3d 726, 735 (Cal. Ct. App. 1986) (no harm can result from failure to warn of risk already known); *see also Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 (Cal. Ct. App. 1992) (no duty to warn of risk known to prescribing physician).

[13] *See Motus*, 196 F. Supp. 2d at 997 (granting summary judgment on causation where "Plaintiff never asked" what could have been the "dispositive" question—*i.e.*, whether the

Dr. Giese. It is undisputed that Dr. Giese was the last physician to refill Ms. Raquel's Depakote prescription before E.G.'s conception. He testified that (1) he did not initiate the prescription for Ms. Raquel (Ex. E, Giese Dep. at 12:15-18), (2) his practice was not to change a drug that was working and that for Ms. Raquel "Depakote was working and she liked it." (*Id.* at 45:1-6, 53:25-54:1), (3) he did not recall what he knew about the comparative teratogenicity of Depakote versus other medication (*Id.* at 32:19-33:4), (4) he considered the Pregnancy Categories a way to judge comparative teratogenicity (*Id.*at 147:18-20, 147:23-24, 148:1), and (5) a Black Box warning suggests that the drug is more dangerous than a drug without such a warning (*Id.* at129:16-20, 129:22.)

Dr. Giese likewise did not testify that he would not have prescribed Depakote to Ms. Raquel had he been provided different warnings by Abbott. While he testified that his "prescribing habits" would "[p]robably" have been affected if he had been told that Depakote was a drug of last resort, or was four times more teratogenic than Depakote, that testimony is legally insufficient to establish that these warnings—assuming for argument's sake they were required for adequacy—would have prevented E.G.'s prenatal exposure to Depakote. (*Id.* at 105:14-23, 106:3-4.) Plaintiffs could have asked Dr. Giese at his deposition or live at trial whether this information or any other information would have caused him not to prescribe Depakote for Ms. Raquel. They did not, and this failure precludes them from demonstrating Dr. Giese would not have prescribed Depakote to Ms. Raquel.

Dr. Han. Dr. Han was the only one of Ms. Raquel's four prescribing physicians Plaintiffs called live at trial. He testified that if had been given different warnings in the 2006 Depakote label, he likely would have advised Ms. Raquel to try another medication instead of Depakote,

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prescriber would have prescribed Zoloft to plaintiff's decedent if he had been given the warnings plaintiff proposed).

and told her of an increased risk. However, his testimony would not permit a reasonable jury to conclude that different warnings would have led to a different outcome in this case for three reasons. First, the issue is spina bifida, not other birth defects. Any serendipitous causal link between failure to warn about one injury (birth defects other than spina bifida) and the occurrence *of a different injury* (spina bifida) is too speculative and tenuous to constitute legally sufficient proof of causation, particularly when the injury actually at issue was adequately warned about.[14] That conclusion is supported by California law judging the adequacy of a warning by reference to the plaintiff's *specific injury*, and Plaintiffs' contrary argument would constitute an expansion of California law this Court should not undertake.[15]

In addition, Dr. Han did not testify that in the face of different warnings he would have refused to prescribe Depakote for Ms. Raquel. When directly asked if he would have told Ms. Raquel she could not take Depakote and taken it away from her, he answered, "No." (Ex. G, 6/5/07 Trial Tr. at 1231:9-17.) Since Plaintiffs chose not to not bring Ms. Raquel to trial, there is no evidence in the record that she would have stopped taking Depakote on Dr. Han's recommendation (the only evidence is to the contrary), or that the risk of birth defects played any role in her decision-making.

In short, Plaintiffs' failed to provide legally sufficient evidence that different warnings likely would have changed the outcome in this case.

B. No reasonable jury could find that Abbott's marketing or promotional activities were a substantial factor in causing E.G.'s injuries, nor is this evidence relevant to their negligent failure to warn case.

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[14] *See Cochran v. Wyeth*, 3 A.3d 673, 680-81 (Sup. Ct. Pa. 2010) (plaintiffs could not establish causation where physician testified he would not have prescribe drug had he known of the risk of one injury when that risk never manifested and plaintiff suffered a different injury);

[15] *See* cases cited, *supra*, at nn. 2-3, 5-6.

Plaintiffs devoted considerable trial time to playing deposition testimony from Abbott pertaining to sales and marketing. They also questioned Dr. Han about whether sales representatives gave him information from the North American pregnancy registry about a 10% overall risk of birth defects. (*See, e.g.*, Ex. G, Han Testimony at 39.) None of this evidence raises a fact issue on any relevant issue. The law does not require a pharmaceutical company to provide warnings via sales representatives. Nor is there any evidence—much less legally sufficient evidence—that any marketing or promotional activities played any causal role in Ms. Raquel's use of Depakote at the time of E.G.'s conception. Thus, even if Plaintiffs had provided legally sufficient evidence that Abbott was negligent in its marketing or promotional communications (and they did not), no reasonable jury could find that such communications were a substantial factor in causing the injuries in this case.[16]

III. No reasonable jury could find by clear and convincing evidence that Abbott engaged in malice, oppression, or fraud that caused E.G.'s injuries, or constitutionally impose punitive damages in this case.

The Court has indicated it will submit punitive damages if there is a liability finding. Plaintiffs' proof in their case-in chief is not legally sufficient clear and convincing evidence demonstrating entitlement to punitive damages as a matter of California substantive law and federal due process. Abbott warned of the precise injury sued for in a Black Box, which alone precludes punitive damages. The California statute permits a punitive damage award only "where it is proven by clear and convincing evidence that the defendant has been guilty of

[16] *Id.* at 998-99 (rejecting "overpromotion" argument where alleged activity did not cause the decision to prescribe); *See also Huntman v. Danek Medical, Inc.*, 1998 WL 663362, at * 6 (S.D. Cal., July 24, 1998) (rejecting overpromotion and off-label promotion theories where "plaintiffs fails to adequately differentiate between defendants' conduct in the marketing of the TSRH system and the treating physician's independent medical decision to use the TSRH screws for pedicle fixation.").

oppression, fraud, or malice."[17] Conduct warranting punitive damages must be far above mere negligence or even gross negligence: it must be despicable, or malicious, or deceitful.[18]

Plaintiffs' evidence falls far short. None of Plaintiffs' evidence about marketing and sales, or other putative "profits over safety" evidence, demonstrates a state of mind indicative of malice, oppression, or fraud as defined by California law. Plaintiffs' suggestion that Abbott concealed information about the overall incidence of birth defects from the North American Pregnancy registry is factually inaccurate and is not the stuff of punitive damages in any event. Critically, none of the conduct Plaintiffs' claim is blameworthy is causally tied to the injury in this case, where Abbott adequately warned about the very injury at issue. Federal due process does not permit a jury to punish Abbott for conduct that *did not cause E.G.'s injuries*.[19] And "[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis."

To impose punitive damages on these facts would be factually unsupported and constitutionally infirm. Accordingly, in addition to Abbott's previously-stated reasons for opposing the presentation of punitive damages under Rule 54, Abbott requests judgment as a matter of law under Rule 50(a) on punitive damages.

CONCLUSION AND PRAYER

A reasonable jury would not have a legally sufficient evidentiary basis to find for Plaintiffs under Fed. R. Civ. P. 50(a). Abbott asks the Court to enter complete judgment as a

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[17] Cal. Civ. Code § 3294.

[18] *See Kendall Yacht Corp. v. United Cal. Bank*, 123 Cal. Rptr. 848, 854 (Cal. Ct. App. 1975).

[19] *See State Farm Mut. Auto. Ins. v. Campbell*, 538 U.S. 408, 420 (2003); *see also BMW of North America v. Gore*, 517 U.S. 599, 572-73 (1996).

matter of law in its favor. Alternatively, it asks for partial judgment as a matter of law as to Plaintiffs' (1) negligent failure-to-warn claim based on spina bifida, and (2) punitive damages.

Date: June 6, 2017

Respectfully submitted,
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 6, 2017, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

/s/ Dan H. Ball